



Certificate of analysis

Productname: :Lopinavir

Cas number: 192725-17-0

Molecular Formula: C₃₇H₄₈N₄O₅

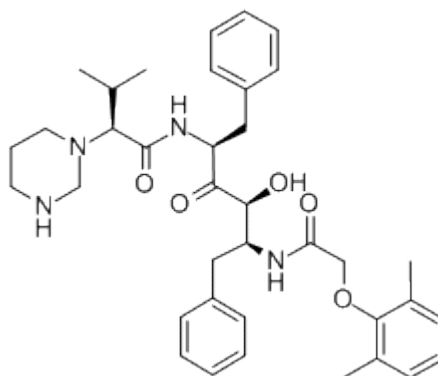
Molecular Weight: 628.80

Date of production:Mar, 02, 2020

Batch NO:20200302

Exp Date: Mar, 01, 2022

Chemical structure:



Items	Specifications		Results
Appearance	White powder		White powder
Identification	HPLC:The retention time of the test sample corresponds to that of the reference standard		conforms
	IR : The infrared absorption spectre of the test sample is concordant with the spectrum of the reference standard		conforms
Water	$\leq 4.4\%$		4.1%
Residue on ignition	$\leq 0.20\%$		0.03%
Heavy metals	$\leq 20\text{ppm}$		conforms
Residual solvents	Ethanol $\leq 5000\text{ppm}$		200ppm
	Ethyl acetate $\leq 5000\text{ppm}$		N.D
	Dimethylformide $\leq 880\text{ppm}$		N.D
	2-propanol $\leq 5000\text{ppm}$		N.D
	N-heptane $\leq 5000\text{ppm}$		320ppm
	Triethylamine $\leq 720\text{ppm}$		N.D
Related substances (By HPLC)	Impurity 1	Impurity b (RRT=0.07) $\leq 0.20\%$	N.D
		Impurity I (RRT=1.10) $\leq 0.20\%$	N.D
		Any other impurity $\leq 0.10\%$	0.06%
	Impurity 2	Any other impurity $\leq 0.10\%$	0.07%
	Total impurities from Procedure 1 and Procedure 2 $\leq 0.70\%$		0.45%
Assay by HPLC	98%~102.0%		99.7%

Conclusion:It complies with the USP42 Standard.

Analyst:Zhao

Checker:Liu

Q.C Director. Fang F